

**REMARKS**

Claims 1-12 are pending. Claims 5, is canceled by Applicant without prejudice to later pursuing the claimed subject matter in another application. Claims 1-4, 6-10 have been newly amended. Claims 11-12 are newly added. Support for these amendments is found throughout the specification. No new matter has been entered.

***35 U.S.C. § 112 Rejections*****Indefiniteness**

Claims 1-3, 7 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the office action states that claim 1 is indefinite because it is directed to a “nucleic acid molecule” but each of the steps (a)-(f) are directed to “nucleic acid molecules”. Similarly dependent claims 2 and 3 are also directed to nucleic acid molecules.

Accordingly, Applicant has amended claim 1 and claims 2 and 3, so that they are directed to a nucleic acid molecule.

Further, the office action states that claim 7 is indefinite because it lacks antecedent basis for the recited limitation “the CGFP”, and that claim 10 is indefinite because it lacks antecedent basis for the recited limitation “the fluorescent protein CGFP”. Applicant has amended claims 7 and 10 to overcome this lack of antecedent basis.

The office action states that claim 10 is indefinite because it recites a use without any active positive steps delimiting how this use is actually practiced. While Applicant disagrees with the rejection, in the interest of furthering prosecution, Applicant has amended claim 10 so that it clearly encompasses positive active steps.

**Written Description**

Claims 1-3 and 6-9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicant respectfully traverses the rejection. To satisfy the written description requirement, patents must describe the technology that is sought to be patented so as “to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based,

and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). The inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure (*In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96).

Applicant notes that claim 1, sections (a) and (b), are not indicated by the office action as failing to meet the written description requirement. With respect to the remaining nucleic acid molecules encompassed by claims 1-3, the office action states that there are no examples of sequences of these nucleic acid molecules, that an enormous number of nucleic acids are encompassed, and that the nucleic acids of claim 1(d) through (f) and the proteins they encode are structurally distinct and unrelated to each other. Applicants have deleted parts (d) and (f) of claim 1, rendering that portion of the rejection moot.

Part (e) of claim 1 is drawn to a nucleic acid molecule which has 95% homology to SEQ ID NO:1 and encodes a fluorescent protein. This claim language meets the written description requirements as evidenced by Example 14 in the USPTO's training materials. There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of nucleic acid molecules encode proteins that must be variants of SEQ ID NO:1 does not have substantial variation since all nucleic acid molecules encode fluorescent proteins and must have at least 95% homology to the reference sequence nucleic acid sequence of SEQ ID NO:1. The single species disclosed is representative of the genus because all members have at least 95% structural homology with the nucleic acid molecule of SEQ ID NO:1 and because procedures for making variants of SEQ ID NO:1 which have 95% homology to SEQ ID NO:1 and encode a protein which retain its fluorescent activity are conventional in the art. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus. Therefore the specification provides adequate written description for part (e) of claim 1.

Part (c) of claim 1 is drawn to a nucleic acid molecule with a complementary strand which hybridizes under stringent conditions with a nucleic acid molecule of part (a) or (b) of claim 1 and which encodes a fluorescent protein; the nucleic acid molecule of part (a) encoding a polypeptide having the amino acid sequence of SEQ ID NO:2, and the nucleic acid molecule of part (b) comprising the nucleic acid sequence of SEQ ID NO:1. Parts (a) and (b) of claim 1 are not under rejection with respect to meeting the written description requirements. The

specification discloses a single nucleic acid (SEQ ID NO:1) which encodes a fluorescent protein. The instantly claimed invention is an isolated nucleic acid that hybridizes to SEQ ID NO:1 under highly stringent conditions and encodes a fluorescent protein. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing. There is single disclosed species (the nucleic acid molecule of SEQ ID NO:1) that is within the scope of the claimed genus. There is actual reduction to practice of the disclosed species. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claim because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent conditions in combination with the coding function of the recited nucleic acid molecule and the level of one of skill in the art are adequate to determine that Applicant was in possession of the claimed invention.

Applicant contends that Claims 7 and 8, which have been newly amended to depend from newly amended claim 1, and Claim 6 drawn to a protein encoded by the nucleic acid molecule of claim 1, all meet the written description requirement for the reasons discussed above, as does newly amended Claim 9 drawn to an antibody which specifically binds the protein of claim 6. In *Falkner vs. Inglis*, 448 F.3d. 1357.07 (Fed Circuit 2006) the court had to consider whether claims directed to a vaccine comprising a mutant pox virus were adequately described by Inglis' specification. The court stated that examples were not necessary to support the adequacy of written description, that the written description requirement may be met even where actual reduction to practice of an invention is absent, and that there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

In view of the instant claim amendments and remarks, reconsideration and withdrawal of the rejection is respectfully requested.

### ***Claims Rejections 35 U.S.C. § 101 .***

Claims 1-6 and 9-10 are rejected under 35 U.S.C. 101 on the grounds that the claimed invention is directed to non-statutory subject matter.

Specifically the office action states that in claims 1-3, the nucleic acid molecules are not

isolated and therefore show no hand of man. Applicant has amended claims 1-3 to indicate that the recited nucleic acid molecule is isolated.

The office action further states that in claim 4, the term “organism” is directed to non-statutory subject matter. Applicant has amended claim 4 to recite a host cell which is statutory subject matter.

The office action states that in claim 6 and 9, the recited peptides are not isolated and therefore show no hand of man. Claims 6 and 9 have been amended to show the hand of man by reciting an isolated protein and isolated antibody, respectively.

The office action states that claim 10 is not a proper process claim under 35 U.S.C. 101 because it recites a use but no steps. Applicant has amended claim 10 and therefore traverses the rejection.

In light of the above amendments, reconsideration and withdrawal of the rejection is respectfully requested.

### ***Claims Rejections 35 U.S.C. § 102***

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Michaels (US 5,096,865).

The office action asserts that Michaels teaches a DNA sequence of green fluorescent protein which has more than 10 consecutive nucleotides identical to the instantly claimed SEQ ID NO:1. Applicant respectfully traverses.

However, in order to expedite prosecution, Applicant has cancelled Claim 5 without prejudice, rendering the rejection moot.

Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. Compar. Biochem. Physiol. B. 1982, 72;1:77-86.

The office action asserts that Levine et al. teaches a partially purified green fluorescent protein (phialidin, also known as clytin) isolated from *Phialidium gregarium*. The office action contends that phialidin “is the same protein taught by the instant specification as coming from the same organism with the alternate name, *Clytia gregaria*”, page 10 of the office action dated 3/6/2007.

Applicant respectfully traverses on the grounds that the instantly claimed protein is not the same protein as phialidin. Though Levine et al. does not provide sequence information for phialidin, the molecular weight of phialidin is taught as being  $23,000 \pm 4\%$ , see Abstract on page 77 of Levine et al. Accordingly, Levine et al teaches that the molecular weight of phialidin ranges from 22,080 to 23,920. Liu et al. have crystallized the instantly claimed protein of SEQ ID NO:2 and teach that its molecular weight is 26396.1. See the following websites dated July 17, 2007,:

<http://www.pdb.org/pdb/explore/biologyAndChemistry.do?structureId=2HPW> and

<http://www.pdb.org/pdb/explore.do?structureId=2HPW>

The disparate molecular weights of phialidin and the instantly claimed protein demonstrate that the green fluorescent protein (phialidin) taught by Levine et al does not anticipate the instant claims.

Applicant has amended claims 7 and 8 so that they no longer depend from rejected claim 6, and do not arguably contain subject material that is anticipated by Levine et al. Support for the claim amendments is found on pages 6-7 of the instant specification.

In light of the above amendments, reconsideration and withdrawal of the rejection is respectfully requested.

### ***Conclusion***

Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney's/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

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